

THE BOARD OF PHARMACY

JOINT LEGISLATIVE SUNSET REVIEW COMMITTEE REPORT TO THE CALIFORNIA LEGISLATURE

**Board Overview, Issues, Findings
and Recommendations**

**Prepared by:
Joint Legislative Sunset Review Committee**

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1.

OVERVIEW OF THE CURRENT REGULATORY PROGRAM

BACKGROUND AND DESCRIPTION OF THE BOARD

The State Board of Pharmacy (board) was created by the California Legislature in 1891. The board is responsible for enforcing federal and state laws pertaining to the acquisition, storage, distribution and dispensing of dangerous drugs (including controlled substances) and dangerous devices. The board regulates 12 separate licensure and permit programs for businesses as well as individuals who wholesale and retail those drugs and devices.

Board Composition

The board is composed of 10 members, of which seven are licensed pharmacists and the remaining three are public members. The seven pharmacist members and one public member are appointed by the Governor, while one of the remaining two public members is appointed by the Assembly Speaker and the other is appointed by the Senate Rules Committee. At least five of the seven pharmacist board members must be actively engaged in the practice of pharmacy - and must include one practicing pharmacist from each of the following: an acute care hospital, a community pharmacy, and a long-term care or skilled nursing facility.

Licensing Data

The board licenses over 59,000 licensees and permittees, including 51,667 individuals and 7,600 sites or locations. This includes 28,223 pharmacists, 17,949 technicians, 5,849 pharmacies, 3,569 pharmacy interns, 1,926 exemptees, and 1,751 others (non-resident pharmacies, out-of-state distributors, clinics, medical device retailers, hypodermic needle and syringe distributors, wholesale drug facilities).

BUDGET AND STAFF

Revenue

The main sources of revenue for the board are generated from candidates taking the examinations and for the issuance and renewal of licenses. It is not clear whether there is cross-subsidization between the various program components of the board (e.g., that the fees collected from candidates taking the examination exclusively support the examination program, and that the fees for licensure and renewal of licenses support only the license, enforcement, and administration programs.) However, the board has stated it is planning on having a consultant perform a cost audit of its functions to make the fees commensurate with the service being provided.

Expenditures

The board's projected expenditures for fiscal year 1996/97 are about \$5.2 million. Anticipated revenues are about \$6.9 million, which includes approximately \$1.0 million a year for the next five years, as a repayment of the \$5.4 million that was transferred from the board's special fund to the General Fund to alleviate a shortfall during 1991/92. The board's fund reserve as of June 30, 1996, was about \$2.78 million, or 5.5 months' operating expenses. As of June 30, 1997, the board expects its fund reserve to increase to about \$3.5 million, or about 7.6 months of operating expenses.

The board, by regulation, increased its fees to their statutory limit on July 1, 1995, when it was anticipating an impending fund shortfall in the future and before it was scheduled to receive the return over five years of the 1991/92 fund transfer to the General Fund. The board is now anticipating reducing its fees within its statutorily prescribed limits to reduce its fund reserve, but first plans to have a consultant do a cost audit of all of the board's fees to set them at appropriate levels with respect to the costs of providing the corresponding service.

For fiscal year 1996/97, the board expects to spend \$80,542 on the administration of its examinations, or about 1.6% of its total budget. This does not include salary and wages paid to staff who are assigned to the examination and licensing program. The board expects to spend \$3.95 million on enforcement, or almost 79% of its total budget. This includes the salary and wages for the 31 staff assigned to the enforcement element of the board's administrative program. Other boards spend on average about 7% of their budget on examinations and 66% on enforcement.

The board has 46 staff and 47.9 authorized positions for 1996/97. The enforcement unit has a staff of 31 people, or about 67% of the board's total personnel. The 31 enforcement staff include 2 supervising inspectors and 19 inspectors, all of whom must be licensed pharmacists.

FEES

The board's pharmacist and pharmacy technician licenses are valid for two years. Its other licenses or permits are valid for one year.

LICENSING REQUIREMENTS

To become licensed as a pharmacist in California, a candidate generally must have: (1) a degree from a board-recognized college of pharmacy or university department with 150 or more units and at least a Bachelor of Science degree in pharmacy, (2) obtained 1500 hours of practical experience under the supervision of a pharmacist or preceptor, and (3) passed the state's own pharmacist licensure examination. All of the states and U.S. jurisdictions have licensing requirements similar to those in California.

To become registered (licensed) as a pharmacy technician, a candidate must either: (1) obtained an Associate of Arts degree in a field of study directly related to the duties performed by the pharmacy technician; (2) has completed a course of training specified by the board; (3) is eligible to take the board's pharmacist licensure exam; (4) has satisfactory proof to the board of one year's experience performing the tasks specified for a pharmacy technician while employed or utilized as a pharmacy technician to assist in filling prescriptions for an inpatient in a hospital, for an inmate of a correctional facility, or experience deemed equivalent by the board

The board administers its own state pharmacist licensure examination. However, all other states use the National Association of Boards of Pharmacy licensing exam (NABPLEX). The board believes that the NABPLEX is not a sufficient test of an applicant's ability to actually practice pharmacy but primarily the applicant's academic knowledge. The California exam is task-oriented exam covering activities frequently performed by pharmacists. The examination is given twice year and the passage rate in 1995/96 was between about 45% - 55%.

The only other classification requiring a license examination is the "exemptee" classification. Exemptees are non-pharmacists who oversee board-regulated sites when there is no pharmacist in charge of these sites. Exemptees must pass an exam that is specific for the type of site they will oversee as well as the duties they will perform. There are eight different exemptee exams. The range of passage rate for all exemptees in 1995, was between 31% to 65% for first-time takers.

Foreign-Educated Applicants

Foreign educated applicants must meet the same requirements as any applicant, except that they must: (1) first demonstrate the equivalency of their education to that of domestic graduates by passing a written equivalency examination administered by the National Boards of Pharmacy's Foreign Pharmacy Graduate Equivalency Commission; (2) undergo a foreign graduate evaluation by the board at which the applicant's transcripts are reviewed; (3) complete the 1000 hours of experience requirement as a pharmacy intern under the supervision of a pharmacist or preceptor (600 of which may be waived for documented foreign practice experience); and (4) obtain a score of at least 50 on the Test of Spoken English which is administered worldwide by the Educational Testing Service.

Comity/Reciprocity

California does not give comity to licensees from another state. Pharmacists who are licensed in another state and have worked at least one year may apply to take the pharmacist license exam without submitting the affidavits for 1000 hours of internship, and may become licensed without the additional 500 hours of internship if they can document at least 1500 hours of employment as a pharmacist.

CONTINUING EDUCATION/COMPETENCY REQUIREMENTS

There is a statutory requirement that pharmacists participate in 30 hours of continuing education (CE) every two years as a condition for license renewal. This is the only regulated classification that requires CE for license renewal. The board does not specify the courses but the pharmacy law specifies that these course must be in the form of "postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses and other similar methods of conveying professional pharmaceutical education. The subject matter must be related to health care. The board encourages pharmacists to take a course in geriatric pharmacology, and the board's strategic plan advocates CE courses in patient consultation training and pain management. The board requires an evaluation mechanism be used in CE courses so that participants can assess their achievement regarding a program's learning objectives.

Aside from the above CE requirement for pharmacists, the board does not have a program to assure continuing competence of its licensees. However, the board can and does require remedial education for licensees found to be guilty of incompetence or negligence.

ENFORCEMENT ACTIVITY

The board's enforcement-related activities constitute more than 78% of its workload and expenditures.

The board received 2452 telephone and 257 written inquiries during fiscal year 1995/96. The board has received between 785 to 968 written complaints during each of the last four fiscal years. The board has commenced between 510 and 790 investigations and completed between 480 and 926 investigations during each of the last four fiscal years. The bulk of the board's investigations are completed in between one half to two years. The filed between 56 to 63 accusations during each of the last four fiscal years, closing between 45 to 87 accusations during that same period. The board has experienced a 44% increase in the closure of disciplinary cases since 1992.

Enforcement Data

COMPLAINT DISCLOSURE POLICY

In response to telephone inquiries, the board will provide an oral summary of the number of substantiated complaints against a licensee. If the inquiry is written, the board will provide a written summary of the dispositions of any substantiated, jurisdictional complaint it has received in the previous 5 years.

The board will provide information regarding disciplinary action against a licensee to a requesting party once an accusation has been filed by the Attorney General. Formal disciplinary actions are matters of public record as are the names, license numbers, address of record, date of original licensure, and current license status.

COST RECOVERY AND RESTITUTION TO CONSUMERS

The board was the first licensing board in the Department of Consumer Affairs to obtain disciplinary cost recovery authority (1983.) On average the board collects \$87,000 yearly in cost recovery, or 70% of the amount awarded in a case. The chart below reflects the amount of cost recovery the board has requested and received over the past four fiscal years

COST RECOVERY	FY 1992/93	FY 1993/94	FY 1994/95	FY 1995/96
Requested (Fiscal Year)	\$ 51,048	\$ 125, 495	\$ 200,141	\$ 98,229

COST RECOVERY	1993	1994	1995	1996
Received (Calendar year)	\$ 83,500	\$ 87,799	\$ 103,793	\$88,788

The board's report did not provide any data regarding restitution to consumers as a result of the board's disciplinary actions.

CONSUMER OUTREACH AND EDUCATION

The board has a number of free educational materials to advise and educate the public about the safe use of medications, the value of talking to a pharmacist and the role of the Board of Pharmacy. These materials, as well as the board's written complaint form are available on the Internet at www.rx.ca.gov/rx. In 1995 the board implemented a public information program to educate consumers about pharmaceutical care and the role played by pharmacists. The program consists of educational brochures, speakers, a public service announcement video and special events such as co-sponsoring "Ask a Pharmacist" events throughout the state.

2.

IDENTIFIED ISSUES AND FINAL RECOMMENDATIONS OF THE JOINT LEGISLATIVE SUNSET REVIEW COMMITTEE

ISSUE #1. Should the licensing of pharmacists be continued?

Recommendation: *The State should continue to license pharmacists.*

Comment: Consumers rely on pharmacists for a broad range of critical services requiring professional judgment and complex, technical skills which, if performed incompetently, could cause patient harm or death. The dispensing and distribution of dangerous drugs and devices by pharmacists must be carefully monitored, controlled, and regulated to minimize problems of abuse, misuse, health care fraud and illegal drug trafficking (diversion). The practice of pharmacy is regulated in all 50 states.

ISSUE #2. Should the licensing of other classifications regulated by the Board be continued?

Recommendation: *The licensing and regulation of other classifications currently regulated by the Board of Pharmacy should be continued.*
Also recommend that regulatory authority of other state agencies over certain licensing classifications be consolidated under the Board of Pharmacy. The Board should also consolidate any overlapping or duplicative licensure requirements for any of its licensing classifications.

Comment: The Board also licenses and regulates pharmacy technicians and interns, “exemptees” who are non-pharmacists (who oversee board-regulated sites when there is not pharmacist in charge of these sites), pharmacy premises, non-resident pharmacies which ship or mail drugs, pharmacy clinics, out-of-state distributors, medical device retailers, and drug wholesalers. There is a problem with some overlap in its regulation of certain classifications with other state agencies, and even within its own program (e.g., medical device retailers).

ISSUE #3. Should an independent Board of Pharmacy be continued, or should its operations and functions be assumed by the Department of Consumer Affairs?

Recommendation: *The Board of Pharmacy should be retained as a state agency to administer the pharmacy regulation laws. Legislation should be enacted to continue the Board and require a subsequent sunset review in six years.*

Comment: The Board has demonstrated a high degree of innovation and constructive organizational changes to increase productivity and effectiveness. It has one of the better reputations within the Department of Consumer Affairs (DCA) as a proactive and well administered regulatory agency. There does not appear to be any compelling reason to believe that there would be cost savings or increased performance were the Board to be sunsetted and its functions assumed by the Department.

ISSUE #4. Should the composition of the Board be changed?

Recommendation: *Recommend increasing public membership on the Board by one. The Administration should also attempt to assure that all professional members of the Board are representative of all aspects of the pharmacy profession.*

Comment: There are a majority of professionals on the Board, with a total of 10 members: 7 licensed pharmacists, and 3 public members. DCA generally recommends a public majority and an odd number of members on regulatory boards, or at least achieving greater representation of the public where current board composition is heavily weighted in favor of the profession. DCA believes that the addition of one public member would improve balance consistent with those guidelines. There is also some question as to whether all of the current 7 licensed pharmacists on the Board adequately represents the different practice settings of pharmacy. There are a substantial number of pharmacists who work within different job settings who should be accorded some representation on the Board.

ISSUE #5. Should the current requirement that inspectors employed by the Board of Pharmacy be licensed pharmacists be eliminated? Should the Board's inspectors be granted limited peace officer status as recommended by the Board?

Recommendation: *The requirement that all inspectors for the Board be licensed pharmacists should be eliminated. The inspectors should not be granted sworn peace officer status.*

Comment: The Board should have the option to hire licensed pharmacist inspectors or other state investigators. Mandating that all inspectors be licensed pharmacists is unique to this Board. Other boards do not require that only licensed professionals perform investigation or inspection of suspected violations of their respective licensing acts. Most will use expert professional witnesses as needed. Maintaining 21 licensed pharmacists as inspectors on staff is both costly, and could cause potential problems for the Board in attempting to recruit inspectors (investigators) in the future. Any reclassification of these inspectors, such as providing peace officer status, would increase the overall costs to the Board. (The Board's enforcement program is already above the average spent by other boards -- almost 80% of its total budget.) The Division of Investigation can provide investigators with sworn peace officer status if the need arises.

ISSUE #6. Should the Board of Pharmacy be allowed to hire limited term "in-house" attorneys to prosecute cases on behalf of the Board, rather than using the Office of the Attorney General?

Recommendation: *A pilot project should be established which would allow the Board of Pharmacy, and possibly other boards as determined, to hire limited term staff attorneys to prosecute disciplinary cases. The Department should report to the Legislature comparing the results with those of using the current system.*

Comment: The Board has made efforts in recent years to streamline and speed up its enforcement process. However, it continues to experience significant delays and high costs because of its reliance on the Attorney General's Office (AG) for prosecution of its disciplinary cases. The Board has recommended that they be allowed to establish a core of attorneys knowledgeable about pharmacy law, and policies pertaining to the Board. The Board indicated that this arrangement would improve the time to discipline a licensee and control prosecution costs. DCA believes that a pilot study could settle the debate regarding the effectiveness of in-house attorneys versus those of the Attorney General's Office. (This has been an ongoing issue for the Department and the Boards for many years.)

ISSUE #7. Should an electronic tracking system be implemented, as recommended by the Board, to obtain timely, accurate and complete data for preventing drug diversion of controlled substances?

Recommendation: *The Joint Committee supports the Board's recommendation as long as the Board complies with all mandated requirements to implement any new technology project.*

Comment: The Committee and DCA supports the application of technology when it will improve the efficiency and effectiveness of any Board. However, the Board must comply with the requirements of the Government Code and the State Administrative Manual to implement an electronic tracking system.

ISSUE #8. Should funding be provided, as recommended by the Board, to implement a public education program for consumers regarding the importance of talking to pharmacist about their medications, and the role of the Board of Pharmacy as a consumer protection agency?

Recommendation: *The Joint Committee recommends that the Budget Change Proposal submitted by the Board to obtain funding to implement a Public Awareness Campaign be approved by the Legislature.*

Comment: The Board has submitted a Budget Change Proposal request for approval of limited-term funding for two years (\$263,000 in 1997/98 and \$304,000 for 1998/99). This proposal is included in the Governor's Budget for Fiscal Year 1997/98. The approval of this proposal would permit the Board to design and implement a Public Communication and Education Program, and require the Board to report back to the Legislature and the Administration on its effectiveness before on-going funding is provided.

ISSUE #9. Should the Board be allowed to receive Federal FBI fingerprint reports to check on criminal histories of applicants?

Recommendation: *The Board should be allowed to receive Federal FBI fingerprint checks for criminal histories of applicants. However, the Board should examine the necessity for all applicants to undergo an FBI check.*

Comment: The Board is recommending that licensing criteria be strengthened by requiring Federal FBI fingerprint checks. DCA supports the Board’s recommendation. The Department is sponsoring legislation to permit many of the agencies within the Department to receive FBI fingerprint checks.

ISSUE #10. Should pharmacy management firms be regulated by the Board of Pharmacy?

Recommendation: *The Joint Committee recommends that further data be provided by the Board to determine the extent of the problem created by these management firms and whether regulation of these firms is warranted.*

Comment: The Board of Pharmacy recommended that pharmacy management firms be regulated by the Board. Information obtained from the Board indicated that pharmacy management firms are hired to perform payroll operations, order and control drugs, as well as other management activities. The Board indicated that some of these firms hire impaired pharmacists and pharmacists that have been disciplined by the Board. DCA and the Joint Committee were not supplied with sufficient data to support the recommendation of the Board at this time.

ISSUE #11. Should non-licensed pharmacy owners be required to take and pass a written examination prior to licensure as recommended by the Board?

Recommendation: *The Joint Committee cannot support the Board’s recommendation to require a written examination for non-licensed pharmacy owners without further justification.*

Comment: Information obtained from the Board indicated that the proposed written examination of non-licensed pharmacy owners would test the owners’ knowledge of the Federal and State laws regarding the control, tracking and dispensing of controlled substances rather than pharmaceutical knowledge. However, there does not appear to be sufficient justification for requiring an examination at this time. There was no evidence provided that non-licensed pharmacy owners are illegally handling or dispensing controlled substances due to their lack of knowledge concerning Federal and State laws. Also, current law requires that there be a “pharmacist-in-charge” at any store (pharmacy) operated by a non-licensed pharmacist.

ISSUE #12. Should an examination be required, as recommended by the Board of Pharmacy, before a pharmacy technician can be registered by the Board?

Recommendation: *The Joint Committee cannot support the Board’s*

*recommendation to require a written examination for
pharmacy technicians without further justification.*

Comment: There are currently several educational requirements which the pharmacy technician must meet before they can be registered (and certified) by the Board. Pharmacy technicians are also supervised by a registered pharmacist and are only allowed to perform “nondiscretionary tasks” within the pharmacy setting. No substantive data was provided by the Board to support this additional barrier to registration for a pharmacy technician. The current requirements appear to be sufficient for purposes of assuring the minimum competency of the pharmacy technician in performing his or her pharmacy related duties.